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NRC ACMUI SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

INTRODUCTION

A revision of 10 CFR Part 35, Medical Use of Byproduct Material, was published on April 24, 2002 (Federal Register Vol. 67(79) 20371-20397). The revision contains new training and experience requirements for individuals to become authorized as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and authorized user (AU). These new requirements provide several options for individuals to become authorized. One option is for individuals to be certified by a specialty board whose certification process includes all the requirements in an alternate pathway. The alternate pathway includes specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. Currently, most specialty boards do not require candidates to meet these specific requirements.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) appointed a subcommittee on training and experience requirements to develop recommendations that would restore board certification as the default pathway for individuals to become authorized as RSO, AMP, or AU. The subcommittee held a meeting on June 21 in Rockville, Maryland to discuss draft recommendations and to receive public input. The following recommendations were developed from the June 21 meeting.

RATIONALE

These recommendations are based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations;
(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing such boards;
(3) It is expected that the currently accepted boards will meet the criteria in (2);
(4) The preceptor concept should be modified to become documentation for completion of a training program rather than a testament to clinical competence; and;
(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

The intent of these recommendations is to provide minimum training and experience requirements for an individual to become an Authorized Medical Physicist (AMP), Authorized Nuclear Pharmacist (ANP), Authorized User (AU), or Radiation Safety Officer (RSO). The objective of these requirements is to assure the safe use of byproduct material used in medical practice.

Several pathways are provided to demonstrate adequate knowledge of the safe use of byproduct material. For AMP, ANP, RSO, and each category of use for AU, adequate knowledge may be demonstrated by obtaining certification by a specialty board. The subcommittee's examination of various specialty board criteria for admission of candidates revealed that few specialty boards meet the specific requirements of revised Part 35. However, the subcommittee concluded that individuals who had completed the certification process by appropriate specialty boards had demonstrated adequate knowledge in the safe use of byproduct material for their specialty. Thus the subcommittee recommends that these boards be specifically listed as approved boards.

Additional specialty boards may be identified in the future. The subcommittee's recommendations include specific criteria for recognition of specialty boards that are not specifically listed. As an alternative to board certification, an individual may demonstrate completion of specified training and experience requirements.

In addition to meeting the minimum training and experience requirements, authorized individuals would be expected to demonstrate training or experience in the use of byproduct material or specific modalities, as appropriate, which are similar to those identified on the licensee's license. This would require a licensee to assure that newly hired authorized individuals have appropriate training and experience and that current authorized individuals receive appropriate training when a new modality is added to the licensee's program.

§ 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require the an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who –

(a) Is certified by:
  (1) American Board of Health Physics in Comprehensive Health Physics;
  (2) American Board of Medical Physics in Medical Health Physics;
  (3) American Board of Science in Nuclear Medicine in Radiation Protection;

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomates:

  (1) To hold a bachelors or graduate degree from an accredited college or university in physical science or biological science with a minimum of 20 college credits in physical science;
  (2) To have five or more years of responsible professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics;
  (3) To provide a written certification from the supervising physicist or RSO that the individual has completed the training and experience described in paragraph (b)(2) of this section; and
  (4) To pass an examination administered by diplomates of the specialty board, which evaluate knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology; or

(c) (1) Has completed a structured educational program consisting of 200 hours of didactic training in the following areas--
  (A) Radiation physics and instrumentation;
  (B) Radiation protection;
  (C) Mathematics pertaining to the use and measurement of radioactivity;
  (D) Radiation biology;

(2) Has one year of full-time radiation safety experience under the supervision of an individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar types(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;
(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
(C) Securing and controlling byproduct material;
(D) Using administrative controls to avoid mistakes in the administration of byproduct materials;
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
(F) Using emergency procedures to control byproduct material; and
(G) Disposing of byproduct material; and

(3) Has provided written certification from the supervising physicist(s) or RSO(s) that the individual has completed the training and experience described in paragraph (c)(1) and (c)(2) of this section; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, the licensee shall require a Radiation Safety Officer to have training in the radiation safety, regulatory issues, emergency procedures, and proposed clinical procedures of any modality for which the licensee seeks authorization. This training requirement may be satisfied by completing training that is supervised by an Authorized Medical Physicist, Authorized User, or Radiation Safety Officer as appropriate, who is authorized for the modality for which the licensee is seeking authorization.

§ 35.51 Training for an Authorized Medical Physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who –

(a) Is certified by the one of the following specialty boards in radiation oncology physics ("radiation oncology physics" understood to be that branch of medical or radiological physics that is applied to clinical practice of radiation oncology)
(1) American Board of Radiology in Therapeutic radiological physics;
(2) American Board of Radiology in Roentgen ray and gamma ray physics;
(3) American Board of Radiology in X-ray and radium physics;
(4) American Board of Radiology in Radiological physics
(5) American Board of Medical Physics in radiation oncology physics; or

(b) Is certified by a specialty board in radiation oncology physics whose certification has been recognized by the Commission and requires all diplomates;

(1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;

(2) To have two years of full-time practical training and/or supervised experience in radiation oncology physics

(i) Under the supervision ofa medical physicist who is certified in radiation oncology physics by the board in question, a board specified in paragraph (a) of this section; or a specialty board recognized by the Commission according to this paragraph (b) of this section

(ii) In a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600

(3) To obtain written certification from a medical physicist, certified by the board in question or a specialty board mentioned in paragraph (a) of this section or recognized by the Commission according to paragraph (b) of this section and who has personal knowledge of the candidate's training and experience, that the individual has satisfactorily completed the training and experience described in paragraph (b)(2) of this section

(4) To successfully pass an examination administered by diplomates of the certification board in question that assesses knowledge and competence in clinical radiation oncology, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery.

Or

(c)

(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body

(2) Has completed 1 year of full-time training in radiation oncology physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the modality in which the individual is seeking authorization in a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable

(3) Has obtained written certification from the supervising medical physicist that the individual has satisfactorily completed the training and experience described in paragraph (c)(2) of this section and identifies the byproduct material modalities included.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized medical physicist must have training in the modality for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of treatment planning system. This training requirement may be satisfied by satisfactorily completing a training program provided by the vendor or by training supervised by an AMP authorized for the modality in which the individual is seeking authorization.

Notes on Rationale for Draft AMP rule language

(1) The intent of this draft rule is that an indivual can become an AMP if (certified by a board mentioned in (a) OR a board recognized by NRC whose certification process complies with (b) OR has alternative training and experience specified in (c)) AND has modality-specific training specified in (d)

(2) Paragraph (b) has been carefully written to encompass the currently active certification in Therapeutic Radiological Physics by ABR (TRP/ABR) and Radiation Oncology Physics by ABMP (ROP/ABMP). It is the intent of this draft that both TRP/ABR and ROP/ABMP must comply with (b).

(3) Regarding preceptor's statements, both TRP/ABR and ROP/ABMP require letters written by certified (not necessarily by board in question) physicists who practice in ROP. For ABMP, the preceptor, who must have personal knowledge of but need not have supervised the T&E, verifies that T&E has been completed. For ABR, the preceptor must have been the supervising physicist and attests that applicant is qualified to take exam. "Satisfactorily completed" seems to cover both. "has personal knowledge of" fits both ABR and ABMP procedures.

(4) Unlike radiation oncology physicians, structured residency programs in ROP have not yet achieved sufficient market penetration to make them the basis for identifying appropppriate boards. Hence (b) tries to articulate basic criteria for acceptable practical training and experience. ROP/ABMP requires 2-6 years of training and/or experience depending on details of graduate degree while TRP/ABR requires 3 years for all degrees. Both require the experience to be supervised by a physicist, certified in ROP but not necessarily by board in question. Hence 2 years seems a reasonable minimum. The experience must take place in a facility offering external beam (not necessarily Co-60 teletherapy) and brachytherapy (could be but required to be remotely-afterloaded or HDR brachytherapy). Stereotactic, which is not universally available (either in Gamma or LINAC forms) is not required. The rationale is that (d) takes care of modality specific issues and that broad training in LINAC radiotherapy and brachytherapy is what really makes for safe byproduct medical physicists. The qualification in (b)(2)(ii), requiring supervision by 35.400 or 35.600, is intended to restrict the training sites to those in Canada or U.S

(5) The alternative pathway requirements are a bit stiffer than the board recognition criteria. However, caution must be used. It is unreasonable to expect that 2 years of training can be obtained in an institution possessing Co-60 teletherapy given how few units are extant. Thus while one of the supervising/preceptor AMP's must be recognized as a full-service or teletherapy AMP on a license, the SOC (Statements of Consideration) should clearly state that hands-on experience with Co-60 is not required except as specified by (d). HDR brachytherapy is sufficiently widespread that one could reasonably expect a significant fraction of the two years to be spent in a setting with HDR under the supervision of an HDR AMP. Since only about 50 gamma stereotactic units (GSR) exist in U.S., the SOC should state that out of the two years experience the minimum requirement is the 1 week vendor course for new users, or its equivalent provided by an institution with a GSR facility and supervised by its GSR AMP. Finally, given limits imposed by American medical practice "demographics", the SOC should state that multiple preceptor statements are acceptable, representing rotations or training experiences in different institutions.

(6) Before committing to any specific language functionally equivalent to (b) and (c) of this proposal, NRC staff should work interactively with ABR and ABMP leaders to insure that the criteria are broad enough to qualify both boards yet restrictive enough to exclude unacceptable training and certification mechanisms. NRC should conduct "dry runs," perhaps using files on past HDR/GSR/tele physicst applications, to find out how well (c) works.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

(b) Is certified as a Nuclear Pharmacist by a Nuclear Pharmacy specialty board whose certification process has been recognized by the Commission and requires all diplomats:

(1) Graduation from a pharmacy program accredited by the American Council On Pharmaceutical Education (ACPE);

(2) Must hold a current, active license to practice pharmacy;

(3) Must provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. A maximum of 2,000 hours can be obtained academically by:

a. Undergraduate courses in nuclear pharmacy: up to a maximum of 1500 hours of credit.
b. Post graduate courses in nuclear pharmacy: up to a maximum of 1500 hours of credit.
c. M.S. or PhD. in nuclear pharmacy: up to 2,000 hours of credit.
d. Successful completion of the Nuclear Pharmacy Certificate Program offered by Purdue University (217 hours) or the Ohio State University (214 hours).

(4) Must obtain a passing grade on the certification examination in nuclear pharmacy administered by diplomats of the certification board in question that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(c) Has completed 700 hours in a structured educational program applicable to consisting of:

(1) Didactic training in the following areas
(A.) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving --
(A) Shipping, receiving, and performing related radiation surveys;
(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;
(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
(D) Using administrative controls to avoid medical events in the administration of byproduct material; and
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(3) Has obtained written certification signed by a board certified nuclear pharmacist (BCNP) or of a preceptor authorized nuclear pharmacist (ANP), that the individual has completed the required training listed in (b) (2) of this section.

Sec. 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.100 to be a physician who--

(a) Is certified in--
(1) Nuclear medicine by the American Board of Nuclear Medicine;
(2) Diagnostic radiology by the American Board of Radiology;
(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;
(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;
(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a medical specialty board whose certification process:
(1) Includes all of the requirements in paragraph (d) of this section;
(2) Requires successful completion with a passing grade of written and oral exams administered by diplomates of the certification board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and
(3)Has been recognized by the Commission or an Agreement State; or

(c) Is an authorized user under Secs. 35.290 or 35.390 or equivalent Agreement State requirements; or

(d)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.190, Sec. 35.290, or Sec. 35.390 or equivalent Agreement State requirements, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Secs. 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency program, written certification signed by the residency program director, that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.290 Training for imaging and localization studies.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.200 to be a physician who--

(a) Is certified in--

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;

(6) Nuclear cardiology by the Certification Board of Nuclear Cardiology; or

(b) Is certified by a medical specialty board whose certification process:

(1) Includes all of the requirements in paragraph (d) of this section;

(2) Requires successful completion with a passing grade of written and oral exams administered by diplomates of the certification board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; and

(3)Has been recognized by the Commission or an Agreement State; or

(c) Is an authorized user under Sec. 35.390 or equivalent Agreement State requirements; or

(d)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum,--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use;
(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, involving–

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
(F) Administering dosages of radioactive drugs to patients or human research subjects; and
(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency program, written certification signed by the residency program director, that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.590 Training for use of sealed sources for diagnosis.

Except as provided in Sec. 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Sec. 35.500 to be a physician, dentist, or podiatrist who–

(a) Is certified in–

1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
(2) Nuclear medicine by the American Board of Nuclear Medicine;
(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission; or

(c) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include--

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology; and
(5) Training in the use of the device for the uses requested.

Proposed Modified Language for Therapy-Related Sections
David Diamond, MD
June 24, 2002

Sec. 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.300 to be a physician who—

(a)(1) Is certified by a medical specialty board whose certification process requires successful completion of a minimum three-year residency program in nuclear medicine or radiation oncology approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Whose residency program director has provided a statement attesting that the above training requirements have been met;

(3) Has passed an examination that tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material; and

(4) Whose certification has been recognized by the Commission; or

(b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. This training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. This work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determined the activity of dosages, and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—
(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131;
(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131. Experience with at least three cases in Category (G)(2) also satisfies the requirement in Category (G)(1);
(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or
(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section. The written certification must be signed by a preceptor authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement state requirements. The preceptor authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

(c) Boards currently recognized by the Commission to meet all the requirements of paragraph (a) of this section include—
(1) The American Board of Nuclear Medicine and the nuclear medicine sections of the American Board of Radiology, the American Osteopathic Board of Radiology, and the Royal College of Physicians and Surgeons of Canada; and

(2) The radiation oncology sections of the American Board of Radiology, the American Osteopathic Board of Radiology, British Royal College of Radiology, and the Canadian Royal College of Radiology.

Sec. 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).

(c)(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. [**competency statement removed].** The written certification must be signed by **[….remainder of paragraph unchanged]**

Sec. 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).

(c)(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. [**competency statement removed].** The written certification must be signed by **[….remainder of paragraph unchanged]**

Sec. 35.490 Training for use of manual brachytherapy sources.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a manual brachytherapy for the uses authorized under Sec. 35.400 to be a physician who-

(a)(1) Is certified by a medical specialty board whose certification process requires successful completion of a minimum three-year residency program in radiation oncology approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Committee on Post-Graduate Training of the American Osteopathic Association. This training must include a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources;

(2) Whose residency program director has provided a statement attesting that the above training requirements have been met;

(3) Has passed an examination that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of high and low dose-rate brachytherapy; and

(4) Whose certification has been recognized by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of manual brachytherapy sources that includes--

(i) 200 hours of classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of

radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement State requirements at a medical institution, involving --

(D) Ordering, receiving, and unpacking radioactive materials Safely and performing the related radiation surveys;

(E) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(F) Maintaining running inventories of material on hand;

(G) Using administrative controls to prevent a medical event involving the use of byproduct material;

(H) Using emergency procedures to control byproduct material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement state requirements, that the individual has satisfactorily completed the requirements in (b)(1) and (b)(2) of this section.

(c) Boards currently recognized by the Commission to meet all the requirements of paragraph (a) of this section for radiation oncology include the American Board of Radiology, the American Osteopathic Board of Radiology, British Royal College of Radiology, and the Canadian Royal College of Radiology.

Sec. 35.491 Training for ophthalmic use of strontium-90.

(b)(3) Has obtained written certification, signed by a preceptor authorized user of meets the requirements in Sec. 35.490, Sec. 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section. **[competency statement removed].**

Sec. 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under Sec. 35.600 to be a physician who—

(a)(1) Is certified by a medical specialty board whose certification process requires successful completion of a minimum three-year residency program in radiation oncology approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Committee on Post-Graduate Training of the American Osteopathic Association;

(2) Whose residency program director has provided a statement attesting that the above training requirements have been met;

(3) Has passed an examination that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; and

(4) Whose certification has been recognized by the Commission; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--

(i) 200 hours of classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements at a medical institution, involving--

(F) Reviewing full calibration measurements and periodic spot-checks;

(G) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(H) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(I) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical

Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section for each type of therapeutic medical unit for which authorized user status is requested. The written certification must be signed by a preceptor authorized user who meets the requirements in Sec. 35.690 (or equivalent Agreement State requirements for an authorized user) for each type of therapeutic medical unit for which authorized user status is requested.

(c) Boards currently recognized by the Commission to meet all the requirements of paragraph (a) of this section for radiation oncology include the American Board of Radiology, the American Osteopathic Board of Radiology, British Royal College of Radiology, and the Canadian Royal College of Radiology.

(d) In addition to meeting the requirements of paragraphs (a) or (b) of this section, an authorized user of a sealed source authorized under 35.600 must have training in the modality for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality in which the individual is seeking authorization.